

## REMARKS

Claims 68-127 and 129-137 are pending in the subject application. Claims 68, 79, 83, 93, 99, 111, 116, 129, and 138 are amended herein and claim 120 is canceled, without prejudice. Applicants submit that the amendments herein introduce no new matter, support therefore being found throughout the application and drawings as originally filed. Favorable reconsideration in light of the amendments and remarks which follow is respectfully requested.

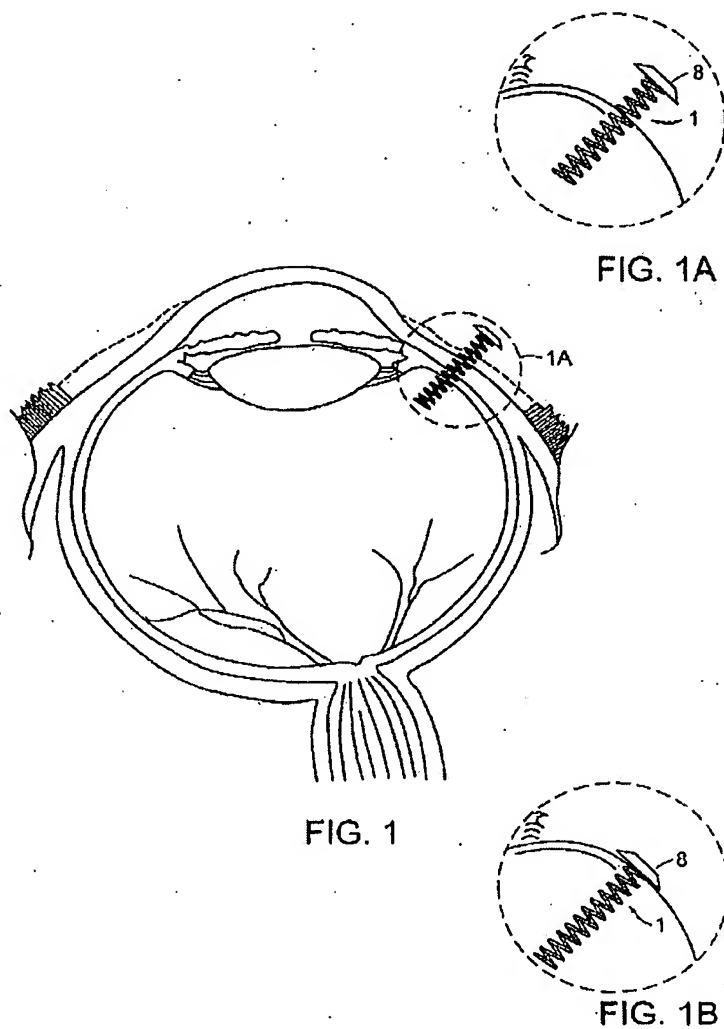
### 1. Specification

The Office suggests that the specification be amended to include the specific language that the cap element is sized to provide a cross-section larger than the cross-section area of the coil or the zig-zag shape or the cross-section of the coil-shaped member, as shown and described in the figures. Applicants have amended the specification herein, as proposed.

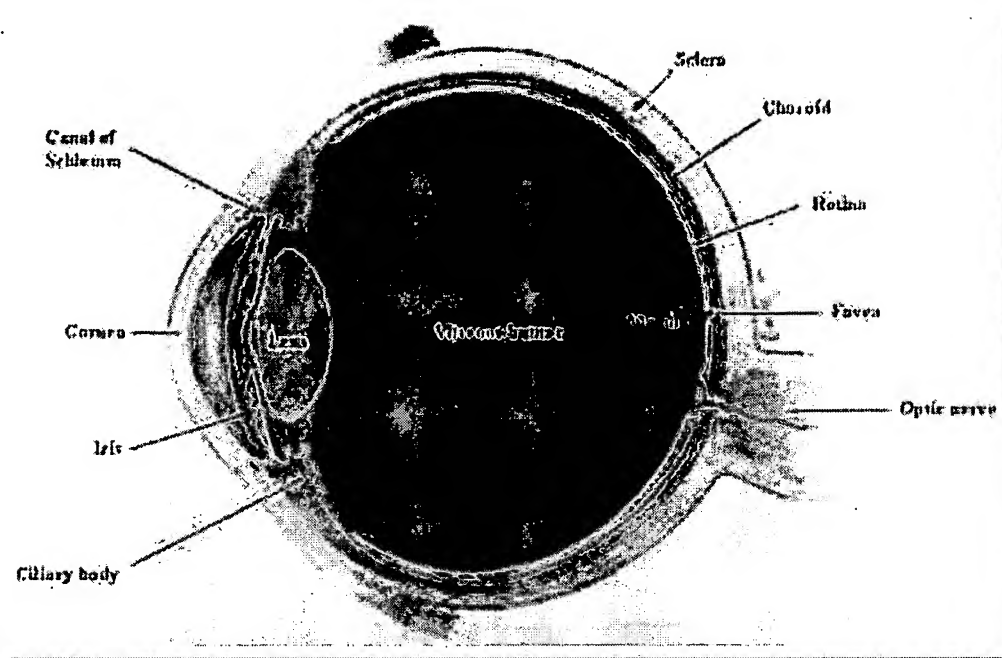
With respect to claims 111 and 116, without agreeing with the rejection, Applicants have amended claims 111 and 116 to recite that the cap element is in contact with the patient eye outer surface rather than the language that “the cap element mates against the patient eye outer surface”. As set out in the disclosure, the device is inserted into the eye with the rim or cap remaining outside of the eye until the rim or cap abuts the incision [0044], and the rim or cap is fabricated of a material that does not cause irritation to the portion of the eye that it contacts [0046]. Thus, Applicants respectfully submit that there is support for a cap element being in contact with the patient eye outer surface. Reconsideration and withdrawal of the rejection is respectfully requested.

With respect to the language “the body member being in contact with intravitreal fluid”, Applicants respectfully submit that this language is clearly supported by the disclosure. In any event, Applicants have modified the claim terminology to refer to “vitreous fluid”. As previously set out, paragraph [0037] sets out that the coil shape of the device provides a large intravitreal surface area through which material can be delivered – intravitreal means within the vitreous. Throughout the disclosure, it is set out that the device is implanted or inserted into the eye through an incision [e.g. see [0014], [0037], [0040], [0045]] and that the device resides

within a patient's eye - particularly the non-linear shaped body member (e.g. see [0002]). This is further depicted in Figs. 1, 1A, and 1B:



The anatomy of the eye, which those of skill in the art are very familiar with, is shown below (as well as in Applicants' Fig. 7):



The vitreous fluid (also commonly referred to as vitreous and vitreous humor) is the clear gel that fills the space between the lens and the retina of the eye. Clearly, the body member of the present device is shown in Figs. 1, 1A, and 1B as being positioned within the vitreous fluid and, as such, would be in contact with vitreous fluid. Applicants have further amended the specification to include this specific claim terminology, which is fully supported by the application as filed. Reconsideration and withdrawal of the rejection is respectfully requested.

## 2. Claim Objections

Claims 99-110, 116-120, 122-127, and 138 have been objected to. Applicants have amended the claims as requested by the Office.

## 3. 35 U.S.C. §103 Rejections

### ***Weiner and Rosenman***

Claims 68-91, 93-97, 99-109, 111-120, 122-127, 129, and 132-138 are rejected under 35 U.S.C. §103(a) over U.S. Patent No. 5,466,233 to Weiner et al. ("Weiner") and U.S. Patent No. 6,478,776 to Rosenman et al. ("Rosenman"). Applicants respectfully traverse.

As acknowledged by the Office, “Weiner et al are silent on the specifics of the tube of the body member comprising a coil or zig-zag shape or being wound into a coil shape”. However, the Office asserts that it would have been obvious to “provide the tube forming the body member of Weiner et al with a coil or zig-zag shape as taught by Rosenman et al as Rosenman et al disclose that it is well known to provide an implantable device with a coil or zig-zag shape so that the device can be properly positioned and maintained in the desired location in a patient’s body”. Applicants respectfully disagree.

Weiner describes a tack for intraocular drug delivery comprising a post 12, an central portion 14, and a head 16 (col. 2, lines 54-56; col. 4, lines 40-41; Figures). The drug to be administered is contained within the post, the central portion is attached to the proximal end of the post, and the head extends from the central portion (col. 2, lines 56-67).

The central portion 14 is configured either as (1) an anchoring region (e.g. as shown in Figs. 1-5) or (2) for ease of or frequent removal (e.g. as shown in Figs. 8-12) (see col. 4, lines 42-50). When provided as an anchoring region, the central portion 14 is provided with a width that varies to anchor the tack in at least one of the sclera, the retina, and the choroids of the eye (see col. 2, lines 61-64; col. 5 line 51 – col. 6 line 11). When provided for ease of or frequent removal, the tack can be secured to the eye by sutures provided through the head 16 (see col. 4, lines 46-50; col. 7, lines 15-28).

According to Weiner, the anchoring region 14a is configured so as to secure the tack into the eye by anchoring it to at least one of the retina, the choroids, or the sclera such that movement of the tack within the eye is minimized (see col. 6, lines 2-11). The post 12 extends from the central portion 14 into the vitreous of the eye (see Figs, col. 3, lines 34-37; col. 8, lines 1-19).

Thus, Weiner teaches a tack for implantation into the eye. The tack includes a post that is positioned within the vitreous of the eye and which houses and delivers a medicinal agent to the

vitreous of the eye. The tack further includes a central portion that can be provided so as to anchor the device in the retina, the choroids, and/or the sclera of the eye.

Rosenman, on the other hand, describes an implant for implantation in the myocardium. The implant is buried in the myocardial tissue and is provided in a shape that fixes the implant in the tissue. For example, the implant can be provided in a helical shape or can be provided with projections extending away from the implant body so as to anchor the implant in the myocardial tissue.

It is respectfully submitted that one of skill in the art would not have been motivated to provide Weiner's post in the form of a helix (e.g. like Rosenman) to maintain and fix Weiner's implant in place within the eye as asserted by the Office. Weiner teaches an implant that is provided with an anchoring region 14a that is positioned within the retina, the choroids, and/or the sclera of the eye (the outer tissue) so as to fix the implant in place. The post 16 of Weiner's implant is the portion that is disposed within the vitreous and which delivers the medicinal agent to the eye. The vitreous of the eye is a gel-like viscous fluid that is composed of 99% water with the balance being salts, sugars, phagocytes, and a network of collagen fibers. Rosenman, on the other hand, provides a device that is implanted completely within solid tissues such that the projections from the device ledge the device in place within the tissues.

There is no teaching or suggestion that providing Weiner's post (which is positioned within this viscous fluid) in a helical shape would provide any benefit and, if so, what. In particular, Weiner's post is provided within the gel-like viscous fluid of the eye – the vitreous fluid – and, thus, this portion of Weiner's device does not hold the device in any particular way within this viscous fluid. Rather, only the anchoring central portion of Weiner's device is provided for holding the device in place within the retina, the choroids, and/or the sclera of the eye. Thus, it would not be obvious to one of skill in the art to modify Weiner in view of Rosenman as proposed by the Office. The only teaching, suggestion, or motivation to provide an ocular implant in the form of a helix comes from Applicants' present disclosure.

In view thereof, it is respectfully submitted that independent claims 68, 79, 83, 93, 99, 111, 116 and 129, and all claims dependent therefrom, are patentable over Weiner and Rosenman. Reconsideration and withdrawal of the rejections is respectfully requested.

***Weiner and Rosenman and Johnson***

Claims 92, 98, and 110 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner, Rosenman, and U.S. Patent No. 5,972,027 to Johnson ("Johnson"). Applicants respectfully traverse.

As set forth above, Weiner and Johnson fail to teach or suggest Applicants' coil or zig-zag shaped implantable ocular drug delivery devices and methods for using. Johnson is cited for allegedly describing shape memory materials. However, Johnson does not remedy the above-noted deficiencies in Weiner and Rosenman.

Accordingly, claims 92, 98, and 110 are patentable over Weiner, Rosenman, and Johnson. Reconsideration and withdrawal of the rejections is respectfully requested.

**CONCLUSION**

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

If for any reason the fee paid is inadequate or credit is owed for any excess fee paid, the Office is hereby authorized and requested to charge Deposit Account No. **04-1105**.

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Respectfully submitted,  
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